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PCT/FR2003/000698

Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference MJPbv598/64	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/FR2003/000698	International filing date (*day/month/year*) 04 mars 2003 (04.03.2003)	Priority date (*day/month/year*) 04 mars 2002 (04.03.2002)
International Patent Classification (IPC) or national classification and IPC C07K 14/~82		
Applicant INSTITUT NATIONAL DE LA SANTE ET DE LA ..ET AL.		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

3. This report is also accompanied by ANNEXES, comprising:

   a. ☐ *(sent to the applicant and to the International Bureau)* a total of _____ sheets, as follows:

      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).

      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

- ☒ Box No. I Basis of the report
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

Date of submission of the demand 29 septembre 2003 (29.09.2003)	Date of completion of this report 26 July 2004 (26.07.2004)
Name and mailing address of the IPEA/EP Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No. PCT/FR2003/000698

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following language _____, which is language of a translation furnished for the purpose of:

☐ international search (under Rules 12.3 and 23.1(b))

☐ publication of the international application (under Rule 12.4)

☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☒ The international application as originally filed/furnished

☒ the description:

pages 1-19, as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☒ the claims:

pages 1-10, as originally filed/furnished

pages* _____, as amended (together with any statement) under Article 19

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☒ the drawings:

pages 1/6-6/6, as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to sequence listing *(specify)*: _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to sequence listing *(specify)*: _____

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

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Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: III.

The present invention lacks unity of invention. None of the additional fees requested have been paid within the time limits by the applicant. Consequently, the international search report is only directed to the invention mentioned first in the claims. In view of PCT Rule 66.1(e), the substantive examination is also limited to the invention mentioned first in the claims.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

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V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-3, 5, 8-10	YES
	Claims	4, 6, 7	NO
Inventive step (IS)	Claims	3	YES
	Claims	1, 2, 4-10	NO
Industrial applicability (IA)	Claims	1-10	YES
	Claims		NO

2. Citations and explanations

Reference is made to the following documents:

D1: WO-A-0190197

D2: WO-A-0021551

D3: European Journal of Immunology, 2001, **31**, 2007-2015

I. Novelty

Document D1 describes a multi-epitope composition (and a polynucleotide coding for said peptide) including at least two peptides of two different categories as defined in claims 1 or 2 (see figure 27, pages 179-180 (peptide I) and pages 201-202 (peptide II)), including respectively the peptides derived from MART (fragment 2), gp100 (fragment 32) and tyros (fragment 21): (peptide I) and the peptides derived from MAGE-3 (fragments 11 and 12) and NYNSO1a (fragments 6 and 7): (peptide 2). Consequently, claims 4, 6 and 7 do not meet the criterion of novelty as defined by PCT Article 33(2).

II. Inventive step

1. Document D2, which is considered the prior art closest to the subject matter of claim 1, describes peptides including an epitope, derived from melanocyte antigens and

presented in the HLA-B35 context, as well as the use thereof to prepare a medical drug for anti-tumour immunotherapy in an HLA-B35 patient or in a diagnostic method for identifying HLA-B35 positive cells (see in particular page 7, lines 11-16; page 11, lines 21-26; claims 1-27).

2. Consequently, the subject matter of claim 1 differs from this known prior art in that a peptide including the EX1AGIGILX2 sequence as defined in claim 1 is used to prepare a medical drug for anti-tumour immunotherapy in an HLA-B35 patient.

3. The problem that the present invention aims to solve can therefore be considered to be that of providing an alternative peptide for preparing a medical drug for anti-tumour immunotherapy in an HLA-B35 patient.

4. The solution proposed in claim 1 of the present application is not considered to be inventive (PCT Article 33(3)) for the following reasons: document D3 describes the identification of six peptides that are restricted by HLA-B3501. One of these peptides is Melan-A/MART-1. Therefore, it is obvious that said peptide includes an epitope presented in the HLA-B35 context. A person skilled in the art is well aware that said Melan-A fragment including said epitope is an equivalent alternative to the peptide defined in claim 1, which can be used in the method according to claim 1. In view of the present techniques, identifying a Melan-A fragment including said epitope is considered to be a routine measure that does not involve an inventive step.

Therefore, claim 1 does not involve an inventive step (PCT Article 33(3)).

5. In view of the disclosure of D2 and D3, the dependent or corresponding claims 2 and 4-10 do not contain any feature which, in combination with those of any one of the claims to which they refer, or per se, defines subject matter that meets the PCT requirements of novelty and/or inventive step.

Nevertheless, the peptides according to claim 3, characterised by SEQ ID Nos. 9-12, are neither suggested nor indicated in the prior art. Consequently, claim 3 (and the other claims in a limited form) is considered to be novel and to involve an inventive step.